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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/827,229 | 04/06/2001 | Zvia Agur | Q63893 | 7712 |

7590 11/17/2004
SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
WASHINGTON, DC 20037-3213

EXAMINER

MORAN, MARJORIE A

| ART UNIT | PAPER NUMBER |
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1631

DATE MAILED: 11/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 09/827,229 | Applicant(s) AGUR ET AL. | |
| | Examiner Marjorie A. Moran | Art Unit 1631 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 18 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-91,98,99,101-113,115-117,332-340 and 347-349 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 66-78,80-91,102-104,106-113,115,116 and 332-340 is/are allowed.
- 6) ☒ Claim(s) 98,99,117 and 347-349 is/are rejected.
- 7) ☒ Claim(s) 79,101 and 105 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. All objections and rejections not reiterated below are hereby withdrawn. Claims 66-91, 98-99, 101-113, 115-117, 332-340, and 347-349 are pending.

Drawings

In view of the amendment to the specification filed 8/18/04, the objection to the drawings is hereby withdrawn.

Claim Objections

Claims 79, 101 and 105 are objected to because of the following informalities: a comma should be inserted after the term "threshold" in line 3 of each of claims 79 and 105. In claim 101, the term "components" should be -- compartments--. Applicant is advised that recitation of the term "components" in claim 101 is presumed to be a typographical error, therefore the claim is not rejected herein for new matter. If applicant does intend a process model which includes a "plurality of components", then applicant is requested to point to specific support in the originally filed specification, by page and line number, for the newly recited limitation. Appropriate correction is required.

Claim Rejections - 35 USC § 103

Claims 98-99, 117, and 347-349 are rejected under 35 U.S.C. 103(a) as being unpatentable over WICHMANN et al. (Cell Tissue Kinetics (1979) vol. 12, pp. 551-567) in view of THOMAS (US 5,879,673).

WICHMANN teaches a system and method of predicting/modeling thrombopoietic lineage in rats wherein his model comprises a progression of cells through compartments S, M, P, and T, wherein the cells in his compartments may be sub-divided (sub-compartmented) into cells of specific ages (pp. 553-554). WICHMANN teaches that his method may be used to model cells involved in thrombocytopenia (pp. 555-556). WICHMANN also teaches that a experimental data regarding stem cell proliferation (i.e. bone marrow progression), platelet counts, and TPO concentration changes may be included in his model (p. 555, Table 1). WHICHMANN further teaches inclusion of cell-suppressive effects in his model (pp. 561-562, Figures 8 and 9). WICHMANN does not teach a model for a general human patient.

THOMAS teaches that models of thrombopoiesis in rodents are “translatable” into human beings; i.e. may be used to model the same disorder/disease in humans. THOMAS also teaches that actual testing of humans is dependent on FDA approval (col. 25, lines 9-22). THOMAS teaches a plurality of treatment protocols for treating chemotherapy-induced thrombocytopenia with TPO in both animals (col. 7 and all Figures) and humans (col. 25, lines 1-20 and col’s 27-28).

It would have been obvious to one of ordinary skill in the art at the time of invention to have translated the model and system of WICHMANN into a system and method to predict thrombopoietic lineage in a human, as suggested by the teaching of THOMAS that rodent models can be translated into human models, where the motivation would have been to model thrombocytopenia-related diseases and predict TPO effects in advance or addition to actual human testing, as suggested by THOMAS' teaching that actual testing of humans is more difficult than in silico modeling. It would further have been obvious to have included the multiple treatment protocols of THOMAS and a selector and/or step of selecting an optimal treatment protocol from the plurality, in the method and system of WICHMANN, where the motivation would have been to select a dosage and timing of TPO administration which raises the platelet nadir and shortens the period of severe thrombocytopenia, as taught by THOMAS (col. 27, lines 1-22 and col. 28, lines 4-28).

Allowable Subject Matter

The following is an examiner's statement of reasons for allowance.

The prior art does not teach or fairly suggest a model or system for modeling thrombopoietic lineage in an individual comprising a process model for cells involved in thrombopoiesis wherein the process model is modified based on parameters specific to the individual, as recited in claims 66 and 332. The prior art does not teach or fairly suggest a system or method for modeling thrombopoietic lineage in a general human patient wherein a process model

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comprises the particular compartments recited in claim 101, or wherein cells pass between compartments each hour, as in claim 115.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Claims 66-78, 80-91, 102-104, 106-113, 115-116, and 332-340 are allowed. Claims 98-99, 117, 347-349 are rejected, and claims 79, 101, and 105 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marjorie A. Moran whose telephone number is (571) 272-0720. The examiner can normally be reached on Mon. to Wed, 7:30-4; Thurs 7:30-6; Fri 7-1 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marjorie A. Moran
Primary Examiner
Art Unit 1631

Marjorie A. Moran
11/12/04